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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/651,307

08/28/2003

Chia-Gee Wang

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EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/651,307	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> ALICIA R. HUGHES	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 115, 122, 124-129 and 136-147 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 115, 122 and 124-129 and 136-147 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 115, 122 and 124-129 and 136-147 are pending and the subject of this Office Action. Applicant cancelled claims 130-135 in its response of 09 April 2009.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's arguments filed on 09 April 2009 have been fully considered but are not deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

### ***Claim Rejections - 35 U.S.C. §112.2***

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 115, 122 and 124-129 and 136-147 are rejected under 35 U.S.C. 112, second paragraph, for indefiniteness. Applicant, in its Remarks filed on 09 April 2009, amended claims 115 and 141, incorporating the language, "said dose being at least  $10^6$  Gy within a few atomic distances from the iodine in the rose Bengal."

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The phraseology "within a few atomic distances" in claims 115 and 141 is a relative term which renders the claim indefinite. The terminology "within a few atomic distances" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The Examiner has considered the Applicant's citations of support from the specification in its most recent response and reviewed the referenced paragraphs to ascertain the definition or lack thereof of the newly claimed language. While the amended terminology in the claims is consistent with wording in the specification, one of skill in the art would not have proper guidance to determine what would be considered as a few atomic distances or a few atomic diameters even. As a result, the claims herein are indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 115, 122 and 124-129 and 136-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,366,801 B1 [hereinafter referred to as “Cash et al”] in view of U.S. Patent No. 5,627,871 [hereinafter referred to as “Wang”] and Ariel et al, “Treatment of Inoperable Cancer of the Liver by Intra-Arterial Radioactive Isotopes and Chemotherapy,” *Cancer*, Vol. 20, No. 5, pages 793-804 (1967)[hereinafter referred to as Ariel et al”].<sup>1</sup>

The teachings of Cash et al, Wang, and Ariel et al from this Office’s action of 09 December 2008, 08 May 2006 and 28 August 2007 and all arguments emanating therefrom, are incorporated herein by reference, in total. Examiner also acknowledges and has considered the Declaration of Dr. C.G. Wang.

Applicants now argue that Cash et al is inapplicable as a reference for obviousness against the current claims, because the reference does not show or suggest the use of line emission x-rays to cause emission of Auger electrons from the iodine in rose bengal accumulated in the lysosomes of cells in a dose of at least  $10^6$  Gy within a few atomic distances from iodine in the rose Bengal whereby to cause disruption of the lysosomes and death of the irradiated cells without destroying surrounding cells but instead teachings the use of heavy elements as X-ray intensifiers. Applicants go further to make the conclusive leap that insofar as Cash et al teach the necessity of limiting the dose of radiation used in its methodology, it teaches away from the a methodology that generates of dose of at least  $10^6$  Gy.

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<sup>1</sup> Cited on the PTO-892 form filed on 08 May 2006.

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The Examiner respectfully disagrees. While Cash et al lacks the specificity of at least  $10^6$  Gy as a radiation dosage in the targeted area, the same is embodied by the teachings in Cash et al when looking to the establishment of a *prima facie* case for obviousness. Applicant does refer to some of the teachings in Cash et al and given the ranges to which Applicant cites, and giving the claims their broadest reasonable interpretation, radiation dosages for the affected area and surrounding tissues are within the purview of Cash et al.

The Applicants further state that the secondary references do not supplement the deficiencies in Cash et al, the primary reference. However, as noted prior the radioactive iodine rose bengal disclosed in Ariel et al is reasonably acceptable as a type of rose bengal to those of skill in the art. Further, the line emission X-ray treatment as set forth in the previous Office Action by way of Cash et al in view of Wang reasonably suggests that the irradiation of iodine within the rose bengal compound type, thereby providing tumor treatment, as claimed in the present invention.

In light of the disclosures, one of ordinary skill in the art would be motivated to utilize rose bengal as an anti-therapeutic agent to treat cancerous tumors. Thus, the combined references teach and make *prima facie* obvious how to use the claimed invention at the time that it was made.

### **Conclusion**

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/  
Primary Examiner, Art Unit 1614